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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,429	11/29/2002	Jane E Aubin	3477.95	6914

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,429	AUBIN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1 and 3-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

Applicant's election with traverse of Group V (claim 2, drawn to a method of increasing differentiation of osteoblasts in a mammal comprising administering to the mammal an ERR alpha agonist) in the reply filed on 26 October 2004 is acknowledged.

The traversal is on the grounds that it would not be an undue burden to examine all of the claims concurrently, such as Groups V to VIII. Applicant argues that no restriction for lack of unity of invention was issued during the international stage and that the instant restriction places a burden on the Applicants to file at least 35 separate applications to pursue the subject matter of the originally filed 15 claims.

Applicant's arguments have been fully considered but are not found persuasive. The instant Groups define inventions, which do not relate to a single general inventive concept because they do not share a special technical feature. For example a method of *administering a nucleotide sequence encoding ERR alpha protein* to increase osteoblast differentiation and a method of *administering an ERR alpha agonist* to increase osteoblast differentiation are not linked by the same feature. In addition, the claims of the instant application encompass different biological functions (increased proliferation, decreased differentiation) and entirely different methods (treating bone disorders, methods of screening for a compounds). Accordingly, the instant Groups are not so linked by the same or corresponding special technical feature as to from a single general inventive concept.

Secondly, the MPEP 1893.03 (d) states if the Examiner finds that a national stage application lacks unity of invention under 1.475, the Examiner may in an Office

Action require the Applicant in the response to that action to elect the invention to which the claims shall be restricted. Lastly, while the purported burden to the Applicants to file divisional applications is truly regretted, it is beyond the resources of the USPTO to permit examination of multiple inventions in a single application.

The requirement is still deemed proper and is therefore made FINAL. Claims 1, 3-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 26 October 2004. Claim 2 is under examination.

Information Disclosure Statement

The information disclosure statement(s) (IDS) filed 09 December 2003 and 23 December 2003 were received and comply with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim is drawn to a method of increasing differentiation of osteoblasts in a mammal comprising administering to the mammal an effective amount of an ERR alpha agonist. The specification teaches that the rat calvaria (RC) cell culture system is an accepted model of bone formation. The Examples teach that inhibition of estrogen related receptor (ERR) alpha expression (using anti-sense nucleotides) blocks the differentiation of RC cells to osteoblasts (page 37, line 30-page 40, line 3). Overexpression of ERR alpha increases differentiation and bone nodule formation of RC cells (page 40, lines 5-26). The specification teaches that ERR alpha is involved in osteoblast differentiation, but it fails to teach *how* ERR alpha is regulated. The instant Examples teach that exogenously added estrogen, vitamin D3 and TGF beta stimulated ERR alpha mRNA expression in RC (page 44, lines 15) but it fails to correlate ERR alpha expression induced by estrogen, vitamin D3 or TGF beta with osteoblast differentiation.

In addition, the term ERR alpha agonist can encompass a large genus such as chemicals, compounds, nucleic acid, lipids, macromolecules, etc. The instant specification fails to indicate that a representative number of structurally related compounds are disclosed and therefore, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and would not know how to make them. The specification does not address how to make and use chemicals, compounds, nucleic acid, lipids, macromolecules, etc that

would bind ERR alpha, or potentiate the binding of ERR alpha or the expression of ERR alpha in a mammal to cause osteoblast differentiation. The specification fails to teach an agonist, binding protein, ligand, etc, which regulates ERR alpha that can be administered to a mammal. The instant specification fails to teach how to increased osteoblast differentiation upon administering an ERR alpha agonist.

Due to the large quantity of experimentation necessary to make and use an ERR alpha agonist for osteoblast differentiation, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite structural limitations of ERR alpha agonist for osteoblast differentiation, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient descriptive support for the genus "ERR alpha agonist". The claimed invention is drawn to a method of increasing differentiation of osteoblasts in a mammal comprising administering an ERR alpha agonist. The instant method requires the use of undisclosed agonists. The specification does not demonstrate possession of

the instant process steps, which require the use of undisclosed compounds (for methods of administering agonists). No structural or functional characteristics of such an agonist are provided, nor is there any indication that Applicant had possession of any ERR alpha agonists. There is insufficient descriptive support for the genus ERR alpha agonists.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

The skilled artisan cannot envision the detailed chemical structure of the encompassed "ERR alpha agonist", and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. The term "ERR alpha agonist" can encompass lipids, antibodies, nucleic acids, chemical analogs, biomolecules and macromolecules. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Due to the breadth of the claim genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the Applicant was in possession of the claimed genus. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Objections

Claim 2 is objected to because the instant claim encompasses non-elected inventions.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
4/6/05

ELIZABETH KEMMERER
PRIMARY EXAMINER